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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,459	10/06/2003	Chris Rundfeldt	NY-HUBR 1230 -US	4494
24972	7590	08/29/2007		
FULBRIGHT & JAWORSKI, LLP			EXAMINER	
666 FIFTH AVE			CLAYTOR, DEIRDRE RENEE	
NEW YORK, NY 10103-3198				
			ART UNIT	PAPER NUMBER
			1617	
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			08/29/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/680,459	<b>Applicant(s)</b> RUNDFELDT ET AL.	
	<b>Examiner</b> Renee Claytor	<b>Art Unit</b> 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 12-17 and 19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-17 and 19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application.                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Arguments***

The amendments to the claims in the response filed on 7/12/2007 have been fully considered. Claims 12-17 and 19 are being examined herein.

It is acknowledged that Applicant's submitted a new specification exemplifying the changes requested in the Objection. However, upon review, the specification still contains a lot of errors and still needs correction. Therefore, the Objection to the Specification stands.

It is acknowledged that Applicant's amended claim 15 in response to the claim objections. However, the language of the claim is still incorrect. Please see the following Claim Objection. The Objection to the Claims still stands.

Applicant's amendments to the claims are sufficient to overcome the 35 USC 102 rejection in Bialer et al. In particular, Applicant's amended the claims to include the limitation of treating "idiopathic" epilepsy in dogs, of which Bialer et al do not teach the treatment of idiopathic epilepsy. However, it is noted that Bialer et al. does teach the treatment of different forms of idiopathic epilepsy in animal models and this claim limitation will be address in the following new rejections below.

Applicant's arguments over the 35 USC 103 rejection have been considered and are not found persuasive. Applicants argue that the combination of Bialer et al. with Thomas is not obvious. Applicants argue that Thomas distinguishes symptomatic and idiopathic epilepsy but that Bialer et al. is not concerned with idiopathic epilepsy and therefore the references should not be combined. This argument is not persuasive

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because as discussed above, Bialer et al. does teach treatment of idiopathic epilepsy. Applicants further argue that Thomas does not teach administration of AWD 131-138, which is the primary drug of the presently claimed invention. The Thomas reference was not supplied for the teaching of AWD 131-138, but to teach that Phenobarbital is used for the treatment of idiopathic epilepsy. Therefore, it would be obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose.

Due to Applicants amendments to the claims, the following new rejections are being made.

### ***Objections***

#### **Specification**

35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are: The way that AWD 131-138 is written should be uniform throughout the specification. In some instances it is written as AWD 131-138 and in others it is written as AWD 131 138. There are also several grammatical errors, as well as spelling errors throughout the specification that should be corrected.

### **Claims**

Claim 15 objected to because of the following informalities: the statement "...from about 1 to about 200 mg (1 kg)..." should read "...from about 1 to about 200 mg per 1 kg....". Appropriate correction is required.

### ***Claim Rejections – 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12-15 and 19 rejected under 35 U.S.C. 103(a) as being unpatentable over Bialer et al. (J Epilepsy Research (Jan 2001) 43, pgs. 11-58) in view of Ross et al. (Neurosci Biobehav Rev, 24 (2000) 639-653) and French (Am J Managed Care, Vol. 7, No. 7, 2001).

Bialer et al. teach that AWD 131-138 treats audiogenic clonic seizures in genetic models of epilepsy (meeting the limitation of claim 12; pg. 12, Section 2.1.1.1). Furthermore, Bialer et al. teaches that AWD 131-138 decreases the number and duration of spontaneous spike-wave discharges in WAG rats, which is a model for absence epilepsy. This decrease in spontaneous spike-wave discharges occurs after oral administration at 3 or 30 mg/kg (meeting the limitation of claims 13-15). Because it is taught that AWD 131-138 has anticonvulsant activities in animal models of epilepsy, it is obviously taught that AWD 131-138 would effectively treat epilepsy regardless of

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when it was diagnosed (meeting the limitation of claim 19). Though Bialer et al. does not teach the treatment of dogs with AWD 131-138 in either the AGS or absence epilepsy models, the treatment of dogs is taught in other models. Therefore, there would be a reasonable expectation of success that AWD 131-138 would be an effective treatment for idiopathic epilepsies.

Bialer et al. does not specifically state that the forms of epilepsies are idiopathic.

Ross et al. teach that AGS is a form of epilepsy associated with generalized seizure displayed by clonic or tonic-clonic seizure activity (see first paragraph of Introduction).

French teaches that clonic or tonic-clonic seizure activity and absence epilepsy are both forms of idiopathic epilepsy (see Role of New AEDs on page S209).

Because Ross et al. and French teach that AGS and absence epilepsy are different forms of idiopathic epilepsy, it would be obvious to a person of ordinary skill in the art at the time of the invention that Bialer et al. is teaching the treatment of different forms of idiopathic epilepsy with AWD 131-138. Though Bialer et al. does not teach the treatment of dogs with AWD 131-138 in either the AGS or absence epilepsy models, the treatment of dogs is taught in other models. Therefore, there would be a reasonable expectation of success that AWD 131-138 would be an effective treatment for idiopathic epilepsies. One would be motivated to treat idiopathic epilepsy with AWD 131-138 with a reasonable expectation of success because it is taught that AWD 131-138 is effective in treating AGS and absence epilepsy, which are both forms of idiopathic epilepsy.

Claims 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bialer et al. (J Epilepsy Research (2001) 43, pgs. 11-58) in view of Ross et al. (Neurosci Biobehav Rev, 24 (2000) 639-653) and French (Am J Managed Care, Vol. 7, No. 7, 2001) as applied to claims 12-15 and 19 above, in view of Thomas (Veterinary Clinics of North America Small Animal Practice (2000), 30, pgs. 183-206).

Bialer et al. teach that AWD 131-138 treats idiopathic epilepsy in dog seizure models as described in the above rejection.

Bialer et al. does not teach the co-administration of another active ingredient.

Thomas et al. teach that Phenobarbital is the initial choice of treatment for idiopathic epilepsy in dogs (meeting the limitations of claims 16-17; pg. 191, Choice of Treatment).

It would be obvious to one having ordinary skill in the art at the time of the invention that AWD 131-138 would be successful in treating idiopathic epilepsy in dogs by the teachings of Bialer et al., which teach that AWD 131-138 is effective in treating animal-models of idiopathic epilepsy. Furthermore, it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose. The idea of combining them flows logically from their having been individually taught in the prior art. In re Kerkhoven, 626 F.2d 846, 205 USPQ 1069, 1072 (CCPA 1980). Therefore, it would be obvious to co-administer another active ingredient such as Phenobarbital because it is useful in the treatment of idiopathic epilepsies as taught by Thomas et al. One would be motivated to administer the combined treatment with a

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reasonable expectation of success because both AWD 131-138 and Phenobarbital are taught to effectively treat idiopathic epilepsy.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

### ***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is 571-272-8394. The examiner can normally be reached on M-F 8:00-4:30.

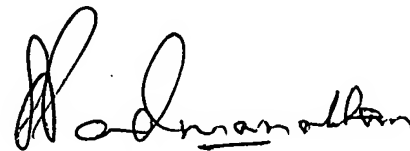


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

A handwritten signature in black ink, appearing to read 'S. Padmanabhan', with a stylized, cursive script.

SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER